Pesticide Program Overview

Office of Pesticide Programs

Office of Enforcement and Compliance Assurance

U.S. Environmental Protection Agency

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Presentation Overview

- US EPA Mission and Responsibilities
- Office of Pesticide Programs (OPP) Overview
  - Pesticide Registration and Registration Review Process
  - Pesticide Product Labeling Management
  - Risk Assessment, Risk Characterization, and Risk Management
  - Reduced Risk Program
  - Establishing Maximum Residue Limits (MRLs)/ Tolerances
  - Inert Ingredient Regulatory Program
  - Other OPP Topics of Interest
- Office of Enforcement and Compliance Assurance (OECA) Overview

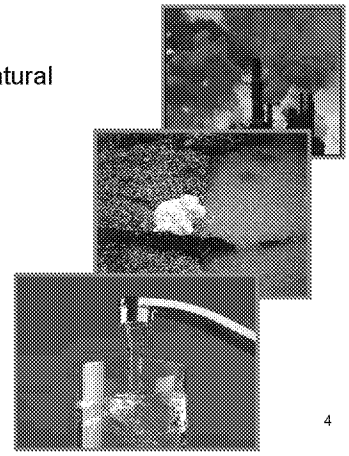
Our Mission and What We Do

Established on December 2, 1970 by President Richard Nixon in the response to the national concerns about environmental pollution*; consolidated a number of functions from several agencies into one agency

EPA's Mission - To protect human health and to safeguard the natural environment -- air, water and land -- upon which life depends

How does EPA accomplish this mission?

- Implement environmental laws (passed by Congress)
- Develop and enforce regulations
- Conduct environmental research
- Facilitate partnerships between private and public sectors
- Provide information to the public
- Provide funding to states and local governments

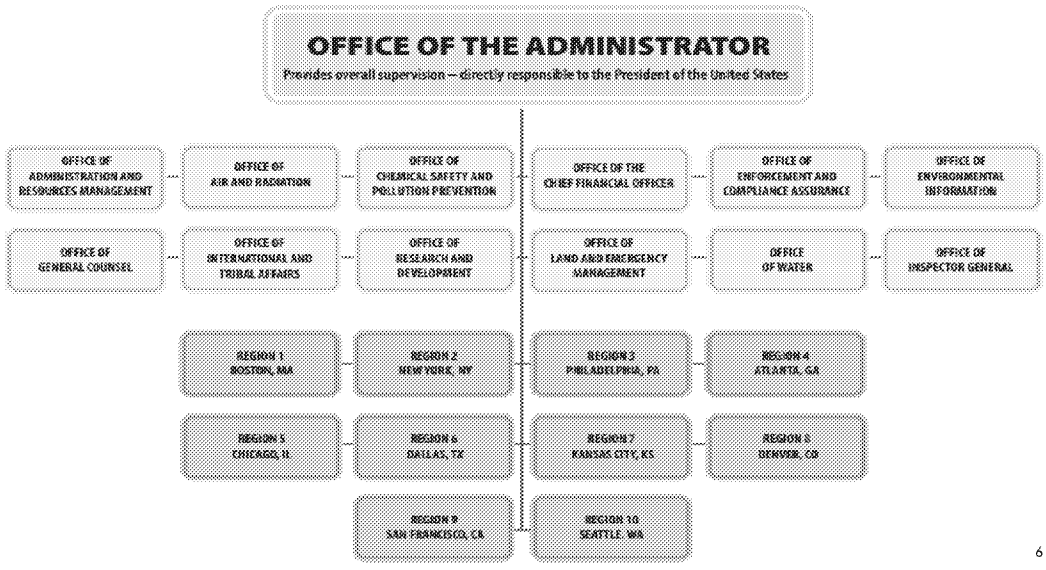


- https://www.epa.gov/history

Who We Are

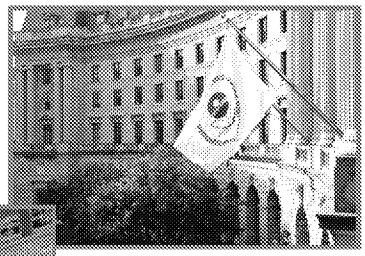
- EPA employs ~15,000 people across the United States
  - Main Headquarters in Washington, DC
  - 10 regional offices and 12 laboratories (throughout the U.S.)
- Our staff are highly educated and technically trained:
  - More than half are engineers, chemists, biologists, toxicologists, microbiologists, entomologists, agronomists, ecologists, life scientists, statisticians, etc
  - Large number of employees are policy analysts, attorneys, public affairs, financial analysts, information management, and computer specialists
- EPA is led by the Administrator, who is appointed by the President

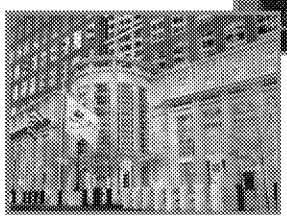
EPA Organizational Structure



EPA Headquarters Responsibilities

- National standards, rules, policies and guidance
- Oversight of state & tribal government authorized programs (e.g. water, pesticide, etc)
- Budget formulation, justification, execution
- National environmental information systems
- Coordination with Cabinet departments
- Research and development
- International activities



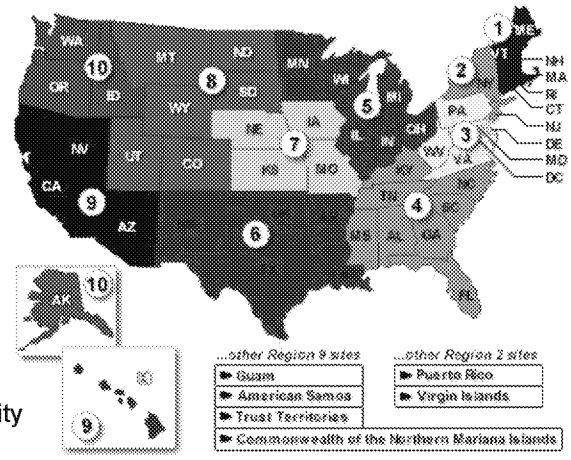


Washington, DC & Arlington, VA

EPA's 10 Regional Offices

Play a key role in EPA-state relations, including:

- Promote innovation and collaboration
- Technical assistance
- State oversight, coordination and support
- Federal inspections, field investigations, and enforcement
- Grants to States
- Superfund cleanups
- Emergency response (e.g. hurricane, etc)
- Environmental Impact Assessments
- Issue permits where EPA has permitting authority



Office of Pesticide Programs

EPA Office of Pesticide Programs (OPP)

- **OPP's Structure and Resources:**
  - One of largest program offices at EPA Headquarters
  - 9 Divisions containing ~600 employees
  - Staff are primarily in Washington, DC but some pesticide liaisons reside in the 10 regional offices
  - Budget >90 million US dollars annually

- **OPP Staff:**
  - Highly educated and technically trained; most have scientific backgrounds including biologists, chemists, toxicologists, geneticists, weed scientists, wildlife biologists, entomologists, plant pathologists, statisticians
  - Support staff include employees with communications, regulatory, financial, information management and computer specialties

Office of Pesticide Programs

EPA

Rick Keigwin, Director
Wynne Miller, Acting Deputy Director
Ed Messina, Acting Deputy Director

Antimicrobials Division
Anita Pease, Acting Director
Neil Anderson, Acting Deputy Director

Pesticide Re-evaluation Division
Yu-Ting Guilaran, Director
Billy Smith, Associate Director

Registration Division
Mike Goodis, Director
Dan Rosenblatt, Deputy Director
Donna Davis, Associate Director

Environmental Fate & Effects Division
Marietta Echeverria, Director
Kimberly Nesci, Deputy Director
Brian Anderson, Associate Director

Biological & Economic Analysis Divison
Wynne Miller, Director
Kevin Costello, Acting Deputy Director

Health Effects Division
Dana Vogel, Director
Elissa Reaves, Acting Deputy Director
Don Wilbur, Acting Associate Director

Information Technology and Resources Management Division
Delores Barber, Director
Hamaad Syed, Deputy Director

Field & External Affairs Division
Jackie Mosby, Director
George (Jeff) Herndon, Deputy Director
Patty Parrott, Associate Deputy Director

Biopesticides & Pollution Prevention Division
Robert McNally, Director
Frank Ellis, Acting Deputy Director

U.S. Pesticide Legislation

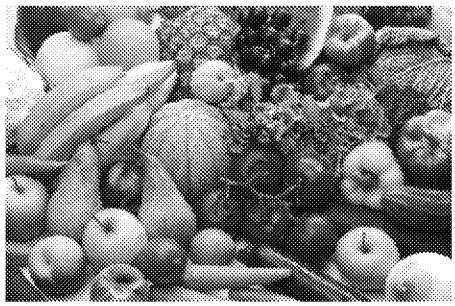
- **Federal Insecticide, Fungicide, and Rodenticide Act** (FIFRA)
  - Registration/Licensing, registration review
- **Federal Food, Drug, and Cosmetic Act** (FFDCA)
  - Tolerances/maximum residue levels (MRLs) for residues in food
- **Food Quality Protection Act** (FQPA)
  - Primarily amended FFDCA by establishing new standard
- **Pesticide Registration Improvement and Renewal Act** (PRIA 1, 2, & 3)
  - Amended FIFRA by adding registration fees and decision review periods
- **Endangered Species Act**
  - Protect endangered wildlife and plants

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Governs the licensing, sale, distribution, and use of pesticides
- Labels ensure safe and proper use of pesticides
- When used according to its label, a pesticide "will not cause unreasonable risk to humans or the environment, considering economic, social, and environmental costs and benefits of the pesticide"
  - Risk-benefit standard: considers **human** and **ecological** risk and requires, for non-dietary risks, the consideration of the **benefits** from the use of the pesticide
- Gives EPA authority to require information (e.g. scientific studies) to be submitted
- Studies sponsored by and paid for by applicant
- EPA can require necessary additional data at any time to support registration

Federal Food, Drug, and Cosmetic Act (FFDCA)

- Governs allowable pesticide residues in/on food:
  - Referred to as tolerances/maximum residue levels (MRLs)
- "A reasonable certainty of no harm" is the general safety standard:
  - Risk-only standard – does not allow the consideration of benefits



EPA Food Quality Protection Act (FQPA)

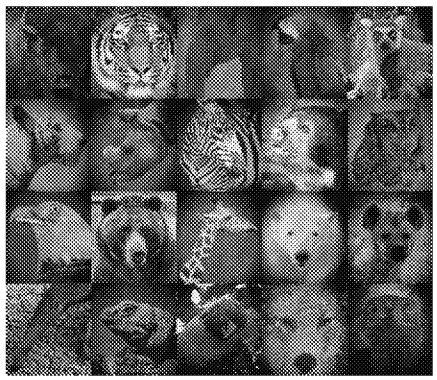
- Amended both FIFRA and FFDCA
- Created the risk-based standard for FFDCA
  - "Reasonable certainty of no harm"
- Imposed stricter standards for tolerance setting including:
  - Enhanced children's protection (FQPA safety factor of 10X)
  - Aggregation of exposures when looking at risk
  - Cumulative assessments
- Required periodic review of pesticides (Registration Review)

Pesticide Registration Improvement Act (PRIA 3)

- Expiration date of PRIA 3 has been extended by the Continuing Resolution signed on 9/28/18, for the duration of that Continuing Resolution period, through 12/7/18.
- The authority to collect maintenance fees at the level specified in PRIA 3, as well as the authority to collect PRIA Registration Service fees at the FY'17 levels, continues through 12/7/18.
- Bills to reauthorize PRIA are pending in Congress.

EPA Endangered Species Act (ESA)

- Protects endangered species from harm resulting from the use of pesticides
- Interaction with Fish and Wildlife Service and the National Marine Fisheries Service



OPP's Responsibilities

- Protect human health and the environment
- Ensure any pesticide residues on food are safe
- Ensure pesticide users have information (*e.g.*, clear label) that allows for proper use
- Ensure decisions reflect the best science and policy judgments
  - Evolving science
  - Endangered species, pollinators, endocrine disruption, human studies are important and challenging science and policy issues
- Meet market needs
  - Industry has timely decisions for their products
  - Farmers and other consumers get products they need
- Meet milestones and statutorily mandated deadlines for regulatory actions

What is a Pesticide?

- EPA requires a substance to be registered as a pesticide if it is intended for a pesticidal purpose.
- Intent of the product can be determined by examining the:
  - Claims on the label and advertising
  - Composition
  - Knowledge that the substance will be used as a pesticide
  - Mode of action of the product as distributed or sold
- So whether a consumer product is regulated as a pesticide depends on the intended use, the claim, if there are exemptions, and if it's covered by another federal agency (like the U.S. Food and Drug Administration or FDA).

Chapter 2 EPA's Label Review Manual: https://www.epa.gov/pesticide-registration/label-review-manual

What is a Pesticide? (cont'd)

- Examples include: insecticides, herbicides, fungicides, plant growth regulators, rodenticides, antimicrobials, biochemicals, plant incorporated protectants (PIPs), etc.

- EPA separates pesticides into three general categories:
  - Conventionals – Registration Division/Pesticide Re-evaluation Division
  - Antimicrobials – Antimicrobials Division
  - Biopesticides – Biopesticides & Pollution Prevention Division

What is a Pesticide Device?

- A pesticide device is an instrument or contrivance that is used to destroy, repel, trap or mitigate a pest
  - Works by physical or mechanical means (such as electricity, light or mechanics) and **does not contain a chemical** to perform its intended pesticidal purpose
  - Registration is not required under Section 3 of FIFRA, however devices are subject to:
    - Section 2(q)(1) and 40 CFR Part 156 with respect to labeling (not allowed to make false claims);
    - Section 7 for establishment registration and reporting;
    - Section 8 –books and records requirements: and,
    - Section 17- imports and exports.

Products not Considered Pesticides for Purposes of FIFRA

- Substances/products excluded from FIFRA registration; 40 CFR 152.6 specifies:
  - **Liquid Chemical Sterilants -** liquid composition, claim as a sterilant and/or plus disinfectant, use site is critical or semi-critical; some regulated by the **FDA**
  - **Nitrogen stabilizers**
  - **Products intended only to aid in the growth of desirable plants** (e.g. plant nutrients)
  - **Products labeled only for use in or on living man or animals** (most covered by **FDA)**
    - **Except** pesticides that kill insects (as opposed to microbes) used on the body. Mosquito repellents, flea and tick remedies for pets, and other insecticides used directly on the living body of humans, pets, and livestock are considered pesticides and are registered by EPA.
  - **Antimicrobial Products Used Solely in Processed Foods or Feeds, in Beverages, or in Pharmaceutical (many regulated by FDA)**

Chapter 2 EPA's Label Review Manual: https://www.epa.gov/pesticide-registration/label-review-manual

Pesticides Exempted from EPA Regulation

- Certain biological control agents regulated by others (except for eukaryotic organisms, procaryotic organisms and viruses)
- Preservatives for biological specimens:
  - Embalming fluids
  - Animal or organ preservation
  - Laboratory sample preservatives (urine, milk, blood, etc).
- Natural cedar
- "Minimum risk pesticides" (if satisfy certain conditions; see Appendix A)
- Certain "treated articles" (per 40 CFR 152.25)

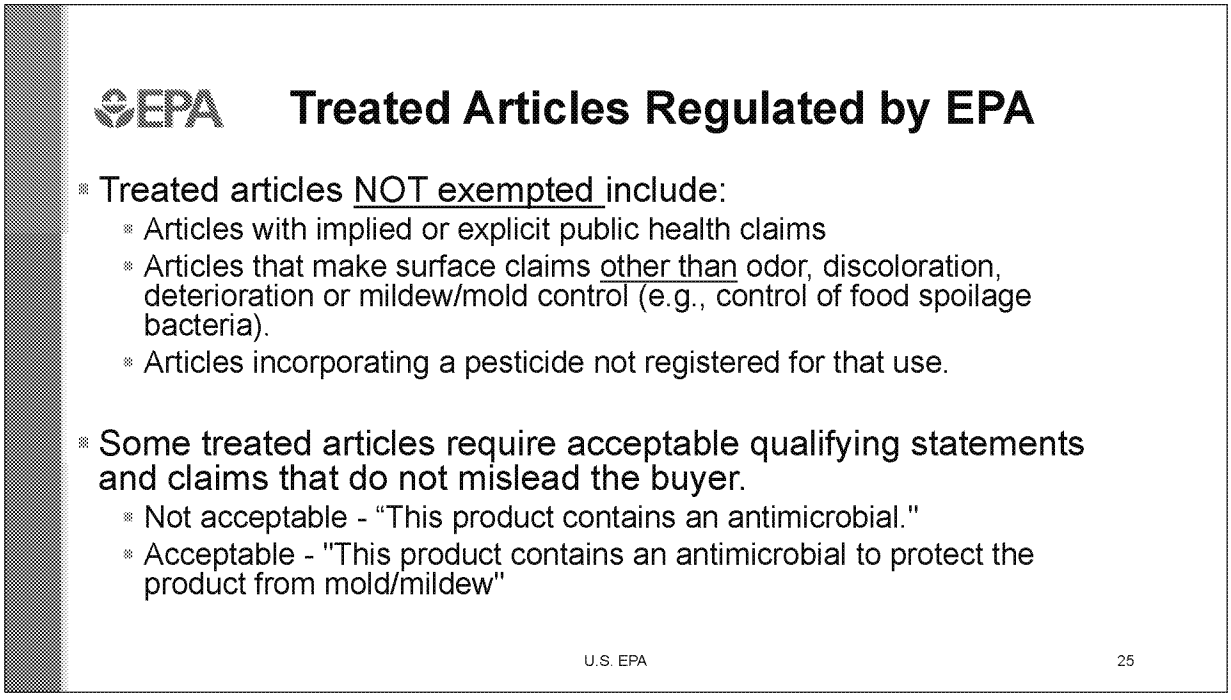
Chapter 2 EPA's Label Review Manual: https://www.epa.gov/pesticide-registration/label-review-manual

Treated Article Exemption

- U.S. EPA has determined that an article or substance containing a pesticide to protect the article or substance itself does not require registration and is exempt from all provisions of FIFRA, provided the pesticide is registered for such use and bears appropriate directions for such use.

- In other words, the sole purpose of treatment is to protect the article or substance itself and any claims must reflect this purpose. Therefore, the article itself is exempt from registration requirements.

- See 40 CFR 152.25(a) and PR Notice 2000-1.



Articles with implied or explicit public health claims; In addition, the name of the product may not contain public health claims.

Surface – second bullet … could say “Articles that make claims beyond protection of the article itself”

Examples of Treated Articles "Not Exempted" and Therefore Subject to EPA Regulation

- Shirts or other clothing treated with an insecticide to repel mosquitoes and other insect pests because the treatment benefits the wearer rather than to protect the clothing (e.g. permethrin-treated clothes).
- Pet collars treated with insecticides (e.g. imidacloprid).
- Paints used in medical settings that claim to kill public health pathogens on a painted surface.

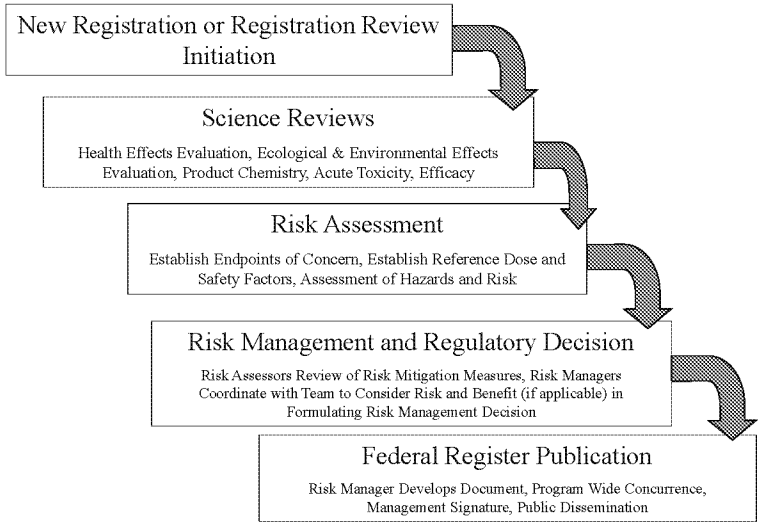
https://www.epa.gov/insect-repellents/repellent-treated-clothing
https://www.epa.gov/pesticide-registration/label-review-manual

Scope of Pesticide Registrations, Registrants and Users

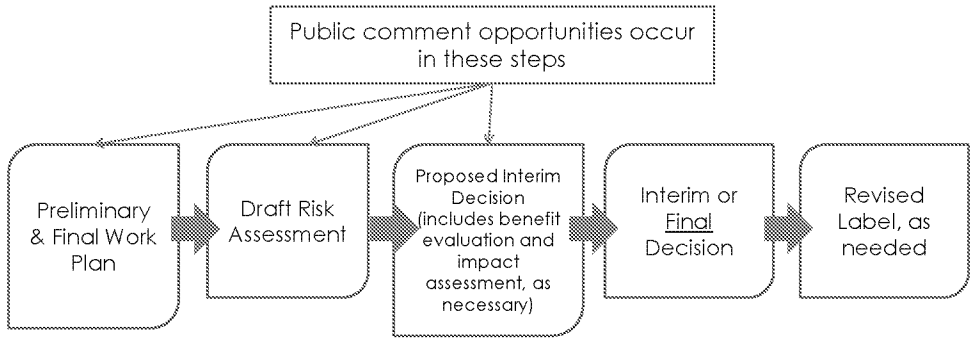
- **Scope of US Pesticide Registrations**
  - Over 1,200 active ingredients, over 16,800 pesticide products, over 16,300 tolerances (maximum allowable pesticide residue on food).
  - Receive/evaluate scientific information/data for >2,000 pesticide applications/year
- **Production and Formulation**
  - 18 major producers, 100 other producers, 2,300 formulators, 20,000 distributors
- **Agriculture Use**
  - 2.2 million farms, 1 million certified applicators
- **Residential Use**
  - 105 million households, 33,000 pest control companies

Pesticide Registration and Registration Review Process

Overall Pesticide Registration and Registration Review Process



Registration Review Process and Public Participation



Registration and Registration Review

- **Registration Process (New Actives and New Uses)**
  - Applicant develops a pesticide, generates data and submits an application for a particular use (or uses) to the EPA
  - EPA reviews submitted data to assess risk and, where appropriate, the benefits associated with a proposed pesticide/use.
  - EPA makes its decision based on all available information
    - Typical application for a new active ingredient includes >100 studies

- **Registration Review**
  - Statutorily required review of pesticides at least every 15 years
  - Intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.
  - EPA must complete first cycle of registration review by Oct. 1, 2022

Registration Responsibilities

Major Registrations

- New active ingredients
- New uses
- Tolerances (MRLs)
- New products
- Amendments
- Notifications
- Inerts
- Minor Uses
- Exclusive Use Petitions

Other Activities

- Section 18 - Emergency Exemptions
- Section 24(c) - Special Local Needs
- Section 5 - Experimental Use Permits
- Efficacy Reviews
- Support Regions, States, and Tribes
- Reduced Risk

Pesticide Product Labeling Management

Pesticide Product "Label" and "Labeling" (FIFRA Section 2(p) Definition)

- **Label**: the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers

- **Labeling**: all labels and all other written, printed, or graphic matter that:
  - accompany the pesticide or device at any time; or
  - to which reference is made on the label or in literature accompanying the pesticide or device "except" to current official publications of the EPA, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

Pesticide Product Labels

- Legally enforceable → all must include statement: "*It is a violation of Federal law to use this product in a manner inconsistent with its labeling.*" In other words, the "label is the law."
- Text on labels is supported by many studies and data that has been evaluated by numerous EPA scientists and committees.
- Provide information about how to safely and legally handle and use pesticide products.
- States in the U.S. are the primary enforcers of the pesticide label.

Labels and labeling are important to OPP …

- Our primary risk management tool for registered pesticides
- Directions and precautions on labels translate our risk assessments into "who, how, where and when" a product can be used safely and effectively
- If not followed or not enforced, our work and regulatory decisions are undermined or nullified

Label and Labeling also Important for …

- Registrants – directions to customers, marketing tool and legal tool for liability concerns.
- Users – how to use the product, how to comply with laws, regulations.
- States to whom EPA delegates enforcement.
- Also, EPA's Office of Enforcement and Compliance Assurance (OECA) and our Regional Offices who support and work with the States on enforcement.

How Does a Label Evolve for a New Registration?

- A company ("registrant") applies for a new product registration, provides a "draft" label, and submits data to support "draft" labeled use
- OPP uses the data submitted to evaluate the risk to humans and the environment, and then decides whether to register the product
- If registered, OPP reviews the label to ensure that it reflects the data that has been submitted to support every statement on the label
- The label must →
  - make sense
  - be clear to the user
  - contain language that is enforceable

Label Changes Are Common

(~5,000 labels reviewed each year by OPP)

- **Company or Registrant Requests Changes (#1 reason):**
  - Addition of new use sites (e.g. orchards, grapes), pests, claims, etc.
  - New names, clarify directions for use, etc.
  - Removal of use sites, pests, uses, etc.
- **State Driven Changes:**
  - Some state like California and NY may be more restrictive
- **EPA Changes:**
  - New rules or policy,
  - Information about pesticide-related incidents via 6(a)(2)
  - Changes in risk a assessment and mitigation

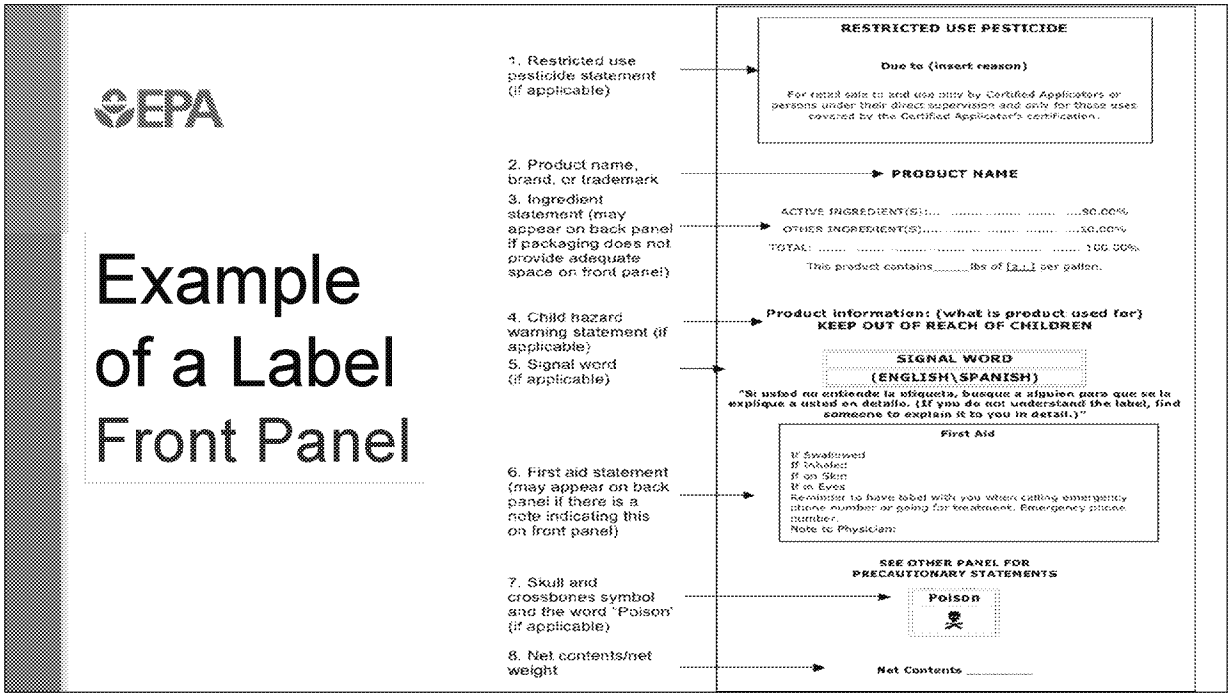
Getting Labeling Right
"Four" Basic Principles

1. Consistency (with EPA Policy and Regulations)
2. Clarity (easy to understand, no jargon, organized format)
3. Accuracy
4. Enforceability
   - ✓ Mandatory vs. Advisory
     - ✓ "Should" means "I don't have to"

- Inaccuracies on the label can increase risks and result in adverse impacts on health and environmental so it's important to get it right.
- EPA's Label Review Manual provides guidance for EPA staff and registrants: http://www.epa.gov/pesticides/regulating/labels/label_review.htm

Summary of Required Label Elements

- Use Classification/Restricted Use Statement (if required)
- Product Name, Brand or Trademark
- Name and Address of Producer or Registrant
- Ingredient Statement
- “Keep Out of Reach of Children” (KOROC)
- Signal Word, including Skull & Crossbones, if either are required
- First Aid Statement
- Precautionary Statements, including Hazards to Humans and Domestic Animals
- Directions for Use
- Misuse Statement
- EPA Registration Number and EPA Establishment Number
- Net Contents/Net Weight
- Storage and Disposal Statements


EPA
Example of a Label
Front Panel
1. Restricted use pesticide statement (if applicable)
2. Product name, brand, or trademark
3. Ingredient statement (may appear on back panel if packaging does not provide adequate space on front panel)
4. Child hazard warning statement (if applicable)
5. Signal word (if applicable)
6. First aid statement (may appear on back panel if there is a note indicating this on front panel)
7. Skull and crossbones symbol and the word "Poison" (if applicable)
8. Net contents/net weight
RESTRICTED USE PESTICIDE
Due to (insert reason)
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.
PRODUCT NAME
ACTIVE INGREDIENT(S):..... ....50.00%
OTHER INGREDIENT(S):..... ....50.00%
TOTAL: 100.00%
This product contains _____ lbs of [a.i.] per gallon.
Product information: (what is product used for)
KEEP OUT OF REACH OF CHILDREN
SIGNAL WORD
(ENGLISH\SPANISH)
"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"
First Aid
If Swallowed
If Inhaled
If on Skin
If in Eyes
Reminder to have label with you when calling emergency phone number or going for treatment. Emergency phone number:
Note to Physician:
SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS
POISON
Net Contents _____

Use Classification

- **General Use Pesticide**
- **Restricted Use Pesticide**
  - Due to human toxicity, ecological effects, etc.
  - Must appear on front panel of labeling and enclosed in box

Basic Label Requirements (cont'd)

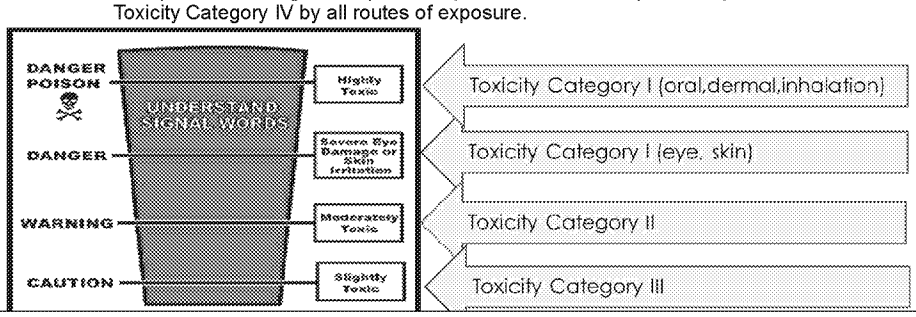
- **Product Name – cannot be misleading**
  - Cannot imply total eradication (e.g., 100% effective, eradicates)
  - Cannot use superlatives (e.g., superior, ultimate, perfect, etc.)
- **Name and address of Producer/Registrant**
  - Must be displayed prominently somewhere on labeling (usually at bottom of front panel)
- **Net Contents/Net Weight**
  - Usually expressed as "Net Weight" or "Net Contents"
- **Product Registration No.** (company and product number separated by a hyphen)
- **Establishment Number**
  - Identifies place of final production
  - State or foreign country designation
- **Misuse statement** - "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

Ingredient Statement

- **Ingredients**
  - Must be clearly presented, preferably on front panel
- **Expressed as the nominal concentration**
- **Headings**
  - "Active Ingredient(s)"
    - Name and percentage of each Active Ingredient (A.I.) must be placed under the heading
  - "Other Ingredients"
    - Total percentage by weight of all inert ingredients ("other") must be placed under the heading.
- **Total of all ingredients must equal 100%.**

Precautionary Statements

- Keep Out of Reach of Children (KOROC)
- Signal Word
  - Determined by most severe toxicity category assigned to the five acute toxicity studies or by the presence of methanol in concentrations of 4% or more
    - Provides information on potential toxicity and irritation
    - Is required for all registered pesticide products unless the pesticide product meets the criteria of Toxicity Category IV by all routes of exposure.



First Aid Statement

- The acute toxicity and product chemistry reviews are used to determine the appropriate First Aid Statement.
- Each product must bear a first aid statement if the product has systemic effects in Category I, II or III, or skin or eye irritation effects in Category I or II.
- A first aid statement must appear on the front panel of all Toxicity Category I pesticides, but EPA allows variations (i.e., back panel, inside booklet) in the placement of the statement for other Toxicity Categories.
  - Tox II and III first aid statements do not need to be immediately visible and can be on an inside panel or any panel. Tox II and III first aid statements need only appear on one panel.
- Refer to EPA Guidance (*PR Notice 2001-1) for additional information.*

Environmental Hazards Statement

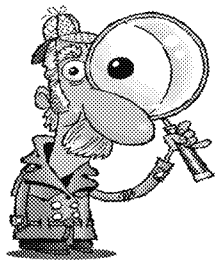
- **Identifies Environmental Hazards**
  - Precautionary language advising of the potential hazards from transport, use, storage, or spill of the product.
  - Hazards may be to water, soil, air, beneficial insects (e.g., honey bees), plants, and/or wildlife
  - Generally based on the result of acute toxicity studies to birds, fish, and aquatic invertebrates.
  - Products used exclusively indoors may omit the statement
  - All products with outdoors uses must have environmental hazards text.
  - May have groundwater advisories

Directions for Use

- The “Directions for Use” portion of a pesticide label describes how the product can legally be used and how the product must not be used.
- Considerations
  - Must be stated in terms which can be easily read and understood.
  - Must be adequate to protect the public from fraud and from personal injury.
  - Must be adequate to prevent unreasonable adverse effects on the environment.
- The human health risk assessments, the efficacy reviews, companion animal safety studies and the ecological assessments all can impact the Directions for Use listed on a product label.

Clear Intention of Statements

- Distinguish the statements that are intended to be enforceable from those that are precautionary or included for informational purposes.
- *If you aren't able to distinguish the difference, applicators and enforcement agents won't be able to either.*
- PR Notice 2000-5 - Mandatory vs. Advisory Labeling Statements (http://www.epa.gov/PR_Notices/pr2000-5.htm)



Mandatory Statements

- Necessary to ensure proper use of a pesticide and to prevent unreasonable adverse effects.
- Directions for use and precautions that direct the user to take or not take specific actions.
- Generally written in ***imperative*** or ***directive*** sentences (e.g., “Do not ..”, “Apply a maximum of…”)

Advisory Statements

- Information on topics such as product characteristics and how to maximize safety and efficacy while using the product.
- Acceptable as long as they:
  - Do not conflict with mandatory statements
  - Are not false or misleading
  - Do not violate statutory or regulatory provisions
- Best written in ***descriptive or nondirective terms, and provide a reason for the desired behavior – not a command***.
- Use of certain words such as “should,” “may” or “recommend” may mislead the user but may be allowed on a case-by-case basis in a clearly advisory statement.

Worker Protection

- **Worker Protection Standard (WPS)**
  - Determine if product is subject to WPS.
    - See OPP Guidance PRN 93-7, 93-11 or the Label Review Manual
  - Non-agricultural use requirements –for uses not in scope of WPS
- **WPS Requirements**
  - General Statements in Agricultural Requirements Use Box
  - Restricted Entry Interval (REI)
    - time period immediately following a pesticide application during which entry into the treated area is restricted
    - based on the most severe acute toxicity category.
  - Notification to workers statements
    - for fumigants used in greenhouses and products classified as toxicity category I.

Worker Protection (cont'd.)

- **WPS – Personal Protective Equipment (PPE)**
  - PPE is required for pesticide handlers and workers who reenter treated areas prior to expiration of the restricted entry interval (REI).
  - Determined by the acute toxicity.
  - PPE includes long sleeves, coveralls, socks, shoes, gloves, respirator, protective eyewear.

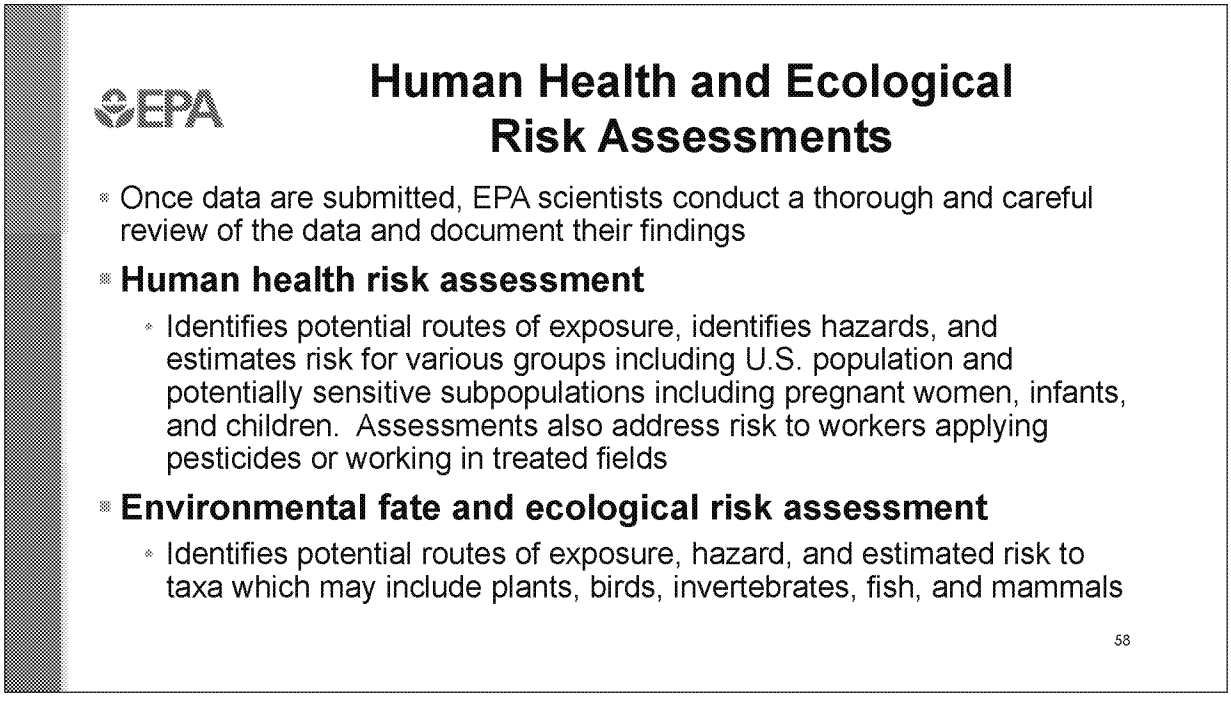
Storage and Disposal Statements

- **Instructions for Storage and Disposal**
  - Required for storage and disposal of pesticides and pesticide containers
  - Statements must be grouped together and should appear near the beginning or end of the directions for use
  - Statements vary depending on the type of product (e.g., residential or commercial use), container, acute toxicity, and active ingredient
- **General statement required for all products unless labeled solely for homeowner use.**
  - "Do not contaminate water, food, or feed by storage and disposal"

Risk Assessment, Risk Characterization, and Risk Management

Types of Data Required for Registration and Registration Review

- Product chemistry to assess labelling
- Product performance data to support labelled pest claims
- Data from studies to determine hazards to companion animals
- Toxicity studies that determine hazard to humans
- Residue chemistry data to determine the nature & magnitude of residues
- Applicator and post-application exposure studies to determine exposure for workers and homeowners (residential)
- Environmental fate data
- Data from studies that determine hazard to non-target organisms



The Evaluation Process

•We evaluate human health risks (including sensitive groups such as children and immune-suppressed individuals), by reviewing data on: ◦ Aggregate risks–through food, water, and residential uses
◦ Cumulative risks–from different pesticides with the same effects
◦ Occupational risks to those applying the product during their work

•We evaluate environmental risks by reviewing data on: ◦ Potential for ground water contamination
◦ Risks to endangered and threatened species
◦ Potential for endocrine-disruption effects

•We implement risk assessment and peer review: ◦ We review all the scientific data on the pesticide product and develop comprehensive risk assessments that examine the potential effects of the product or ingredient on the human population and environment.
◦ The health and environmental risk assessments undergo a process of peer review by scientific experts.

Risk Assessment vs. Risk Characterization

- Risk assessment
  - This process evaluates the potential for human health and ecological effects of a pesticide's use based on hazard and exposure
- Risk characterization
  - This is the quantitative and qualitative evaluation of factors that help risk managers understand:
    - Likelihood of occurrence
    - Nature of the effects of pesticide use
    - Level of confidence and uncertainty

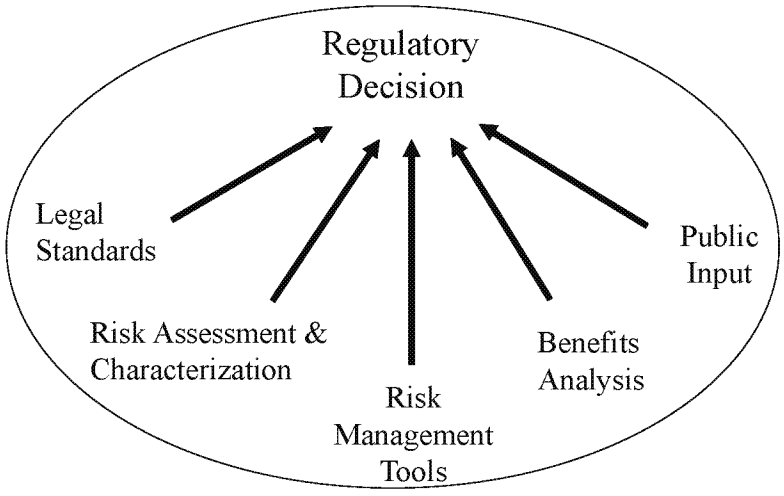
Benefits, Alternatives and Impact Assessments

- **Benefits** - may change over time as new products come on the market and others are retired.
- **Benefits Assessment** - What value does a given pesticide active ingredient provide (i.e. What crops are they used on? what pest(s) does it control?)
- **Alternatives Assessment** - What are the alternatives to control a pest and their risk profile? Will be the overall market be impacted by a regulatory change for a given pesticide?
- **Impact Assessment** – What are the potential economic impacts of regulatory options, such as expected effects on crop yields?
- ***Note:*** A pesticide with small sales numbers can still have high benefits (e.g. use on specialty crops, managing noxious weeds, allows for rotation between different chemistries to avoid resistance, public health benefits like bedbug or rodent control)

Risk Management

- **Risk Management Goals**
  - Ensure that registered pesticides (continue to) meet the statutory standards for protecting human health and the environment
  - Effectively assess, manage and mitigate risks based on best available science and policy, involving stakeholders and the public
- **Risk Managers**
  - Consider the results of the risk assessments
  - Have an understanding of the benefits of a pesticide, as well as alternative pesticides that are already registered
  - Develop measures needed to mitigate any identified risks
  - Negotiate with registrants regarding potential modifications to the product or labeling that must be made to mitigate risk

Risk Management



OPP's Reduced Risk Program

Risk Reduction Program

- Agency initiative to promote the development and registration of lower-risk pesticides
  - Focus ⇒ Conventional Pesticides
- U.S. EPA actively supports registration of new chemistries and technologies that:
  - Reduce environmental loading
  - Provide a more targeted pest strategy
  - Provide better application technology
  - Improves tools for resistance management
  - Provides more favorable human health and/or ecological hazard profiles compared to alternatives
- Shorter PRIA-mandated review timeframe

Overview of OPP's Reduced Risk Screening Process

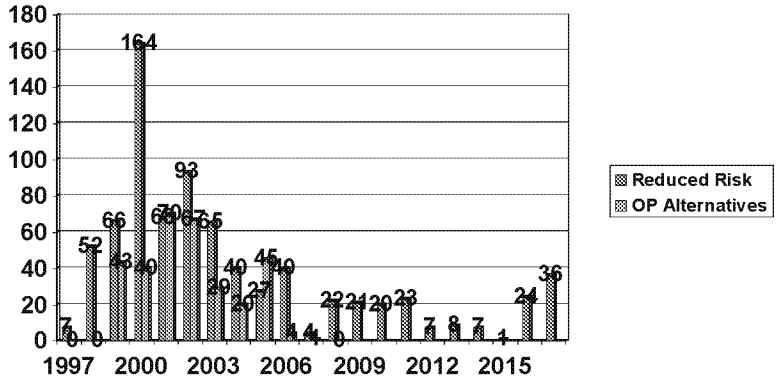
- Applicant prepares an assessment of the chemical and proposed use, comparing risks to those of registered alternatives
- Applicant submits this assessment ("the rationale") at the same time they submit their registration application
- EPA's Reduced-Risk Committee convenes within 30 days to make a determination
- Applicant is notified of decision orally and in writing
- If application rejected, applicant is allowed 30-days from notification to provide a rebuttal
- For rejections related to cancer effects, EPA does not evaluate the rebuttal document until after the further internal evaluation

Reduced-Risk/OP alternatives - New Chemicals

EPA

1994:	2 Reduced Risk / 14 Chemicals	(14%)
1995:	3 Reduced Risk / 18 Chemicals	(17%)
1996:	3 Reduced Risk / **9** Chemicals	(33%)
1997:	4 Reduced Risk / 11 Chemicals	(36%)
1998:	2 Reduced Risk / 13 Chemicals	(15%)
1999:	6 Red. Risk, OP alt. / 12 Chemicals	(50%)
2000:	7 Red. Risk, OP alt. / 11 Chemicals	(64%)
2001:	5 Red. Risk, OP alt. / 12 Chemicals	(42%)
2002:	4 Red. Risk, OP alt. / 12 Chemicals	(33%)
2003:	8 Red. Risk, OP alt / 14 Chemicals	(57%)
2004:	5 Red. Risk, OP alt. / 9 Chemicals	(56%)
2005:	2 Reduced Risk / 8 Chemicals	(25%)
2006:	0 Reduced Risk / 3 Chemicals	(0%)
2007:	2 Reduced Risk / 10 Chemicals	(20%)
2008:	3 Reduced Risk / 8 Chemicals	(38%)
2009:	1 Reduced Risk / 2 Chemicals	(50%)
2010:	1 Reduced Risk / 5 Chemicals	(20%)
2011:	0 Reduced Risk / 4 Chemicals	(0%)
2012:	2 Reduced Risk / 10 Chemicals	(20%)
2013:	0 Reduced Risk / 7 Chemicals	(0%)
2014:	1 Reduced Risk / 5 Chemicals	(20%)
2015:	2 Reduced Risk / 8 Chemicals	(25%)
2016:	0 Reduced Risk / 4 Chemicals	(0%)
2017:	1 Reduced Risk / 6 Chemicals	(17%)

EPA Priorities - New Uses Reduced Risk Organophosphate (OP) Alternatives (1997 – 2017)



Establishing Maximum Residue Limits (MRL)/Tolerances

Reminder about FFDCA and FQPA

- Gives the EPA authority to set limits on the amount of pesticide residues allowed on food or animal feed; these limits are called “tolerances”
- Under section 408, EPA establishes a tolerance (or an exemption from the requirement of a tolerance) for pesticide chemical residues in or on food
- “A reasonable certainty of no harm" is the general safety standard
- Risk-only standard

Establishing Tolerances/MRLs

- Before allowing the use of a pesticide on food crops, EPA sets the amount of pesticide residue allowed to remain in or on each treated food commodity, i.e. tolerances or MRLs, and they are:
  - Set such that actual residues will not exceed this level when applied according to labels
    - Actual crop field trial data with highest application rate and shortest pre-harvest interval (according to the label) are used to support the establishment of tolerances
  - Represent the enforceable levels in food
  - Apply to import, as well as domestic, food
- EPA must ensure that pesticide tolerance level presents a "reasonable certainty of no harm" and considers:
  - Toxicity of the pesticide and its break-down products
  - Amount of the pesticide is applied and how often
  - Amount of the pesticide residue remains in or on food when marketed and prepared
  - All possible routes of exposure to that pesticide

Establishing Tolerances/MRLs (cont'd)

- OPP performs dietary risk assessments that:
  - Considers dietary exposure of infants and children as well as women of reproductive age, ethnic groups and regional populations
  - Uses survey information on food consumption as needed to estimate potential exposure
- OPP combines information about pesticide exposure (from food, drinking water and residential uses) and toxicity to determine potential risks posed by pesticide residues.

U.S. Crop Grouping

- Used to facilitate the establishment of pesticide MRLs for a large number of similar crops based on residue data from selected representative crops
- U.S. EPA is currently in the process on establishing new crop groups and revising older crop groups.
- Benefits of Crop Grouping include:
  - Significant cost savings (each residue trial can cost $110,000 U.S. Dollars)
  - Analytical laboratories can operate more efficiently
  - Minor crop growers obtain labeled uses more quickly
  - Regulatory harmonization can be better realized

Import Tolerance Pilot

- Inspired by import guideline work done in the Asia Pacific Economic Cooperation (APEC)
- U.S. Import Pilot is designed to streamline the establishment of import tolerances by relying on residue chemistry reviews from other national or supranational authorities instead of conducting a new U.S. review
  - Compound generally must have food use registration in the U.S.
  - In-depth review of competent authority's data evaluation report
  - U.S. EPA will conduct an independent human health risk assessment
  - Tolerance = MRL from Codex, EU (European Union), or exporting country

Import Tolerance Pilot (cont'd)

- EPA plans to continue to encourage submissions under this pilot to gain experience with additional national authorities
- At the completion of the currently submitted actions, EPA should be positioned to understand if this can be transitioned to a standard business practice and better informed on the boundaries for a revised import tolerance policy

Overview of Inert Ingredient Regulatory Program

Definition of Pesticide "Inert" (or "Other") Ingredient

- The term "inert ingredient" is defined FIFRA as ". . . an ingredient which is not active" (7 USC§136(m))
- In 1997, EPA allowed the use of the term "other ingredients" in lieu of the term "inert ingredients" on pesticide labels (EPA Guidance Pesticide Registration Notice 97-6)
- EPA regulates the entire product formulation (not just the active ingredient)
  - In the case of food use inert ingredients, EPA requires data to support the establishment of a tolerance (or tolerance exemption) for the inert ingredient under FFDCA
  - EPA also requires data to meet the FIFRA requirements of ensuring the use of inerts in a pesticide product will be consistent with the FIFRA standard.

Operational Definition of Inert Ingredient

- Inert ingredients are intentionally-added components in pesticide product formulations, that do not act as an active ingredient against the targeted pest
- The definition of inert ingredients does not include impurities, degradates, or metabolites
- Inert ingredients have various functions in pesticides (e.g., solvents, carriers, emulsifiers, thickeners, pH control agents)

Inert Ingredient Regulatory Process

- The inert ingredient regulatory program considers both "new" inert ingredients (i.e., not previously approved for use in pesticide formulations) and existing inert ingredients
- Review process of new inert ingredients is similar to active ingredients:
  - Under PRIA, new inert ingredient actions (e.g., request for approval of a new food-use inert ingredient) are subject to fees and timelines as prescribed in the statute.

Overview of Inert Ingredient Data

- Information/data typically to make a decision for a new food use inert ingredient include: physical/chemical properties, toxicity data, metabolism data, exposure/monitoring data ecotoxicity, and environmental fate and effects data.
- While there are no specific inert ingredient data requirements, the data needs for inert ingredients are a subset of the data requirements for pesticides as given in 40 CFR Part 158, which includes:
  - Physical/chemical properties
  - Toxicity data
  - Environmental fates/effect and ecotoxicity

General Approach to Inert Ingredient Dietary Exposure

- Unlike active ingredients, residue data are rarely available for inert ingredients
- In the absence of residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides
- "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at http://www.regulations.gov in docket ID number EPA-HQ-OPP-2008-0738

Dietary Exposure—Residue Levels

- EPA assumes that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity.
- Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient

Considerations for Inert Ingredient Occupational Residential Exposure

- Specific, detailed, pesticide use information (e.g., application rate, method of application, application timing) not available for inert ingredients
- Screening level assessments done for inert ingredient occupational exposure and residential exposure using typical high end exposure scenarios
- Assessments utilize standard assumptions for residential exposures (OPP Residential SOPs): http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf

How are Ecotoxicity Information/Data Used in the Inert Ingredient Evaluation Process

- A full environmental risk assessment is conducted under the Agency's FIFRA authority, therefore the assessment is done on a pesticide product basis (i.e., taking into account the specific uses of the product as given on the product label)
- For inert ingredients, ecotoxicity data and environmental fate data are used to conduct a nontarget organism hazard characterization
- The purpose of the hazard characterization is to identify inert ingredients which, when used in a pesticide product, may result in that product having unreasonable adverse environmental effects and therefore not being eligible for registration under FIFRA

Inert Ingredient Permitted for Use

- InertFinder – An Agency database that provides status information on inert ingredients acceptable for use in pesticides—searchable by chemical name and/or CAS Reg. No. http://iaspub.epa.gov/apex/pesticides/f?p=101:1:
- Trade Name Database -- A database to enhance public access to information related to the EPA approval status of trade name inert ingredients used in pesticide products http://iaspub.epa.gov/apex/pesticides/f?p=inertfinder:mixtures

"Trends" in Inert Ingredients

- Globalization– Pesticide manufacturers desire inert ingredients/formulants that can be used in products used in both domestic and foreign markets
- "21st Century" Risk Assessments – US EPA is an international leader on the use of innovative approaches to assessing the risks of inert ingredients, including the use of (Q)SAR, modeling, and targeted toxicity testing as a way to more effectively and efficiently evaluate inert ingredients
- Novel approaches to assessing inert ingredients with low exposure potential — Utilizing concepts such as the Theoretical Threshold of Concern (TTC) approach, the Agency is seeking to explore processes that will allow for more efficient and effective assessments of inert ingredients with low potential exposures (e.g., components of fragrances used in antimicrobial pesticides)

Other OPP Topics of Interest

Herbicide Resistance Management

- Weed resistance is a serious problem - it does not have clear causes or solutions and therefore extremely difficult to solve
- Affects many important crops, ~70 million acres (USDA), cost estimated at $ 2 billion/year (University of Wisconsin), and is present and more prevalent across all agricultural regions of the U.S.
- No new herbicide Modes of Action have been registered in the U.S. in > 30 years

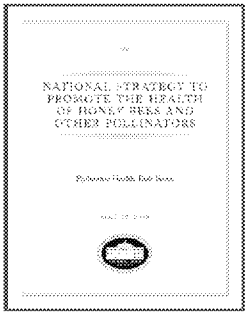
Herbicide Resistance Management Objectives

- Leverage the combined resources of government agencies, commodity groups, cooperative extension services, and industry to focus on the problem of weed resistance to herbicides.
- OPP published guidance for resistance management in 2017:
  - PRN 2017-1 provides general guidance for pesticide labeling to promote resistance management practices.
  - PRN 2017-2 provides specific guidance for herbicide resistance management
- Develop an effective strategy for communicating to U.S. farmers the importance of practicing diversified weed control practices that significantly delay the onset of weed resistance to herbicides.

Presidential Directive to Improve Pollinator Health

- On June 20, 2014, the Administration issued a memorandum calling on federal agencies to increase and coordinate their efforts to improve bee health by developing an integrated strategy

- EPA committed to, among other things:
  - Take appropriate action to reduce risks from the use of products toxic to bees in crops with commercial pollination
  - Engage State and tribal partners in the development of managed pollinator protection plans



EPA Activities on Pollinator Protection

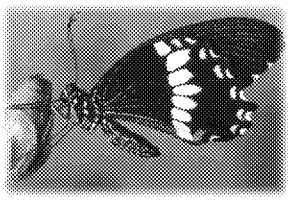
- Assess the effect of pesticides on bees and other pollinators
- Reduce the risks of products toxic to bees in crops with commercial pollination
- Engage State and tribal partners in the development of managed pollinator protection plans
- Expedite review of registration applications for new products targeting pests (*e.g.*, mites) harmful to pollinators
- Encourage the incorporation of pollinator protection and habitat planting activities into green infrastructure and Superfund projects, and
- Enhance pollinator habitat at Federal facilities

Biopesticides: Growth and Trends

- Biopesticides fall into three areas: Biochemicals; Microbials; and Plant-Incorporated Protectants
- Increasing market share over last 15 years
- >400 registered biopesticide active ingredients
- Biopesticides being used in rotation with conventional pesticides
- Marketing opportunities for bee safe biopesticides
- Growing international interest

EPA Biopesticides: Benefits To the Environment

- Less toxic than conventional pesticides
- Generally affect only the target pest and closely related organisms
- Often effective in small quantities
- Decompose quickly = lower exposures to non-targets
- Useful in Integrated Pest Management programs

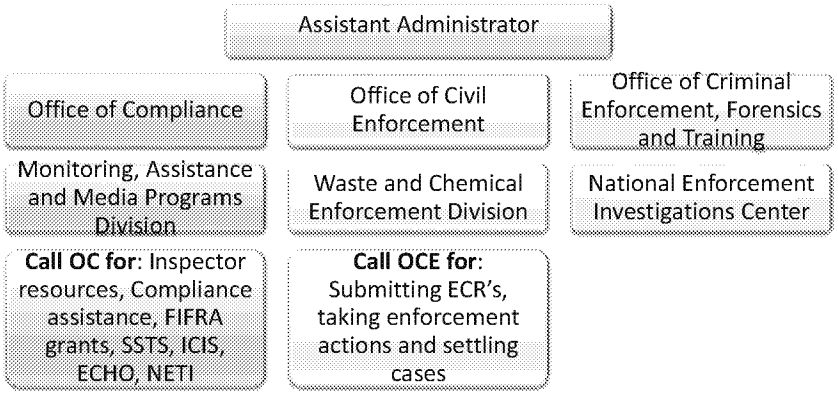


Office of Enforcement and Compliance Assurance

EPA OECA Mission and Responsibilities

- **Enforce environmental laws** to protect human health and the environment
- **Target most serious** air, water, and chemical **hazards**
- Develop, implement, and oversee the Agency's, states', and tribes' **enforcement programs**
- Use a variety of **strategies** to achieve compliance:
  - Compliance assistance, compliance monitoring, civil & criminal enforcement
- **Provide national policies, assistance, training & oversight** to regions, states, and tribes carrying out FIFRA-related compliance & enforcement activities

OECA Organizational Chart

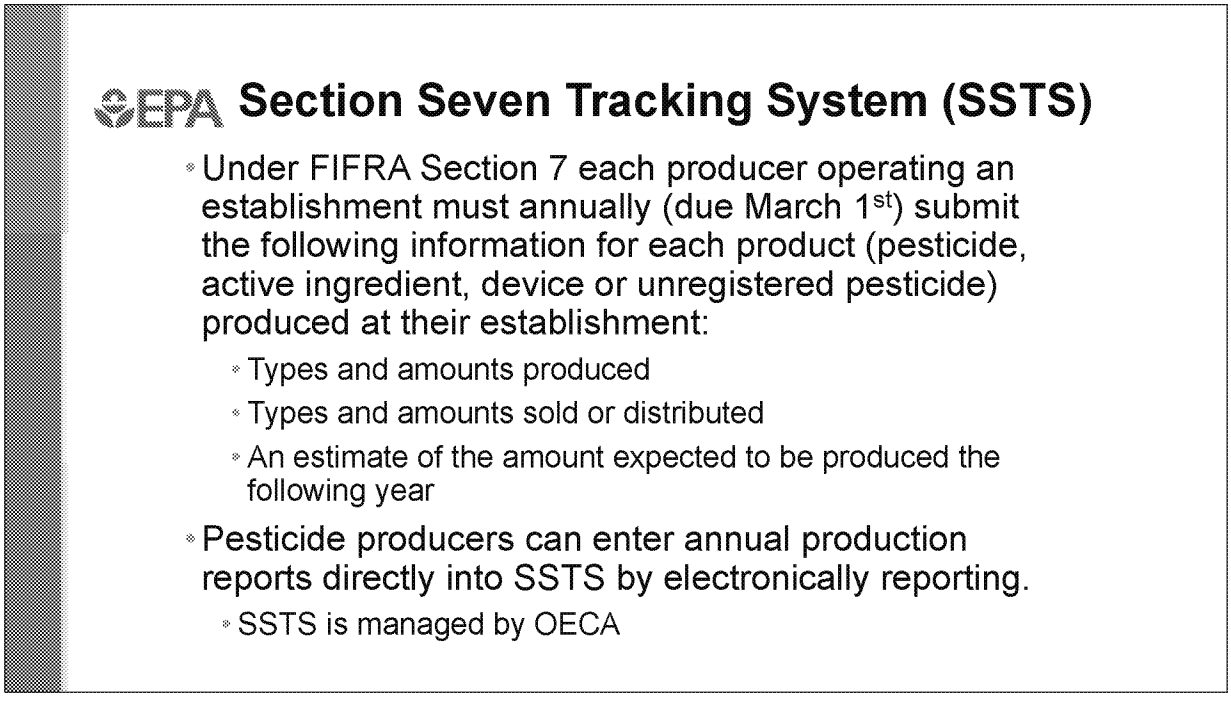


For the most up-to-date contact information follow this link:

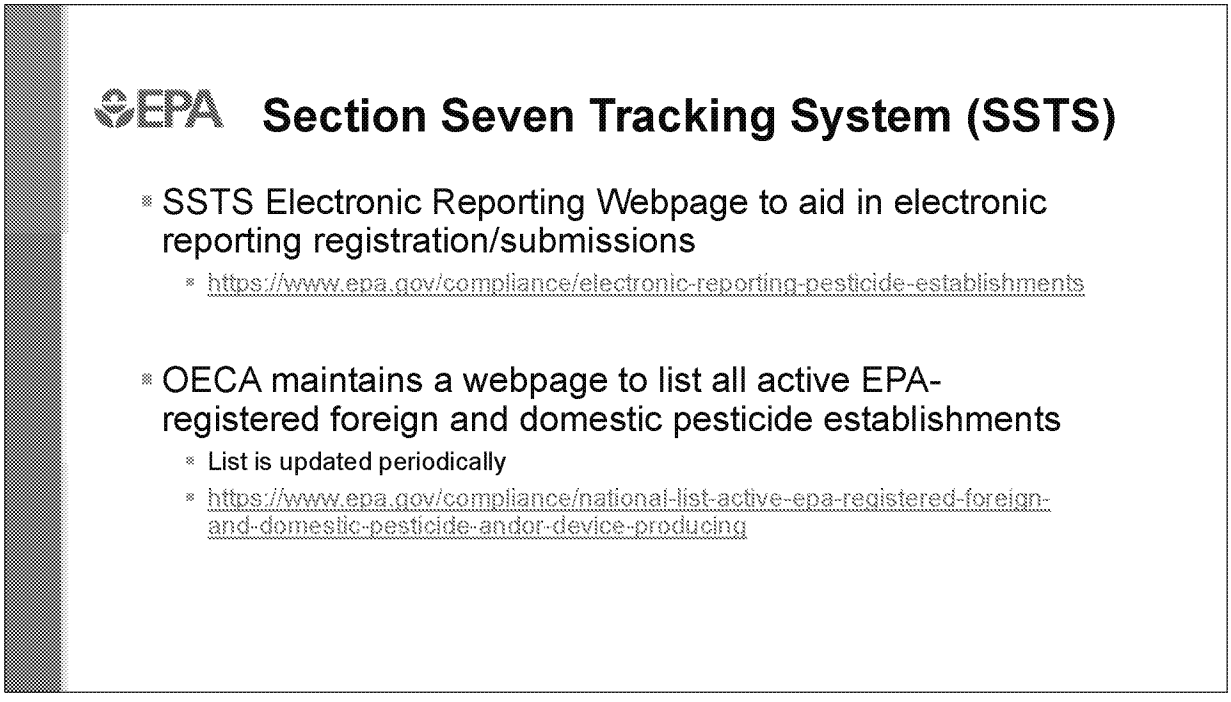
https://www.epa.gov/aboutepa/about-office-enforcement-and-compliance-assurance-oeca

OECA Contacts

- In general, call Office of Compliance (OC):
  - With questions about inspector/investigator training, inspector manuals, requirements, credentials, Inspector Wiki, e-learning courses and questions about FIFRA's Good Laboratory Practice (GLP) program;
  - Questions about offering compliance assistance to regulated entities
  - Questions about an OECA database such as SSTS, ICIS (federal FIFRA enforcement actions and federal inspections), ECHO-Enforcement Compliance History Online;
  - OECA FIFRA grants; and National Enforcement Training Institute (NETI) which facilitates training for federal, state, local and tribal inspectors, investigators, technical experts, and attorneys in civil and criminal enforcement.



Explain What SSTS is using Diagram:
Under FIFRA Section 7 each producer operating an establishment must submit the following information for each product (pesticide, active ingredient, device or unregistered pesticide) produced at their establishment:
Types and amounts produced
Types and amounts sold or distributed, regardless of when the product was produced.
An estimate of the amount expected to be produced the following year
These reports are a critical means of tracking pesticides through commerce and knowing their origins
Traditionally these reports are submitted in hardcopy and are entered into the EPA Section Seven Tracking System (SSTS) manually by EPA employees (Red lines on diagram)
Very time consuming and human error common
Pesticide producers can now enter annual production reports directly into SSTS (BLACK lines on diagram), helping to streamline annual reporting
2016 Reporting Year:
Total of 14,651 Active Establishments globally
Over 40% of all pesticide establishments chose to report electronically with SSTS this year
Over 200 companies have taken advantage of registering new establishments electronically
Allowing companies to enter the marketplace faster

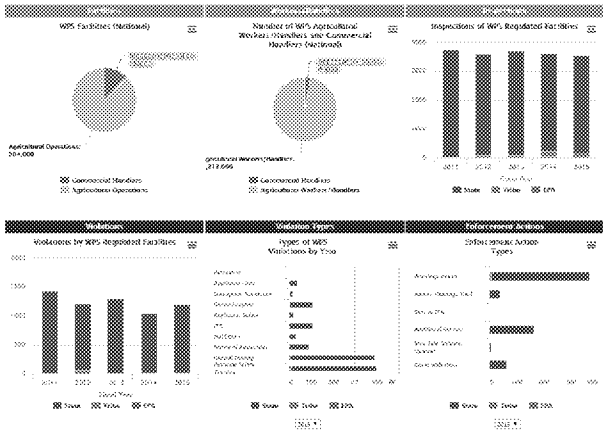


New SSTS Electronic Reporting Webpage, is the central point for information on electronic reporting. The page includes:
detailed instructions on registering for CDX,
Instructions on submitting forms through SSTS
How-to Guides with screenshots,
And Instructional Videos and recorded webinars

Active Pesticide Establishment Webpage:
The file information for each active establishment:
EPA establishment number
Establishment name
Establishment physical site address, state, zip-code, county and EPA region
Establishment Office mailing addresses
Company name
Company headquarters physical site address
Company headquarters mailing addresses
By providing the general public with access to a List of all active EPA-registered pesticide establishment, this page acts as proof that an establishment is registered with the EPA.
Substituting the need for Certificates of Origin (COO)
This page is also helpful for:
reducing number of FOIA requests
Targeting for Producer Establishment Inspections (PEI)

Pesticide State Dashboards

Federal, State and Tribal Pesticide Establishment and WPS accomplishments are publicly available on the ECHO website



Find this information at: https://echo.epa.gov

The State Dashboards on the ECHO website help to expand transparency
The Dashboards can be useful for analyzing annual trends
ECHO Dashboards include information on Air, Drinking Water, Hazardous Waste, Pesticides and Water
The Pesticide State Dashboard includes information on:
Pesticide Establishments: Number of regulated establishments, Inspections conducted and Violations found
Pesticide Worker Protection Standard (WPS):
Facility information: Commercial Handlers or Agricultural Operations
Inspections
Violations found at WPS facilities
Types of WPS Violations
Enforcement Actions taken

OECA Contacts

Additionally, call **Office of Compliance (OC)** for several different media programs:

- Compliance Monitoring – Inspection Manuals, SOPS related to field activities, inspector tools, credentialing, training, targeting research and support, inspector "communities of practice", inspector credentialing and training.
- Compliance Assistance – Compliance Assistance Centers, compliance advisories.
- Databases/data analysis – ICIS (FIFRA enforcement actions and inspections), ECHO – Enforcement Compliance History Online.
- Rulemaking – Promote enforceability of regulations.

FIFRA Inspector Credentials

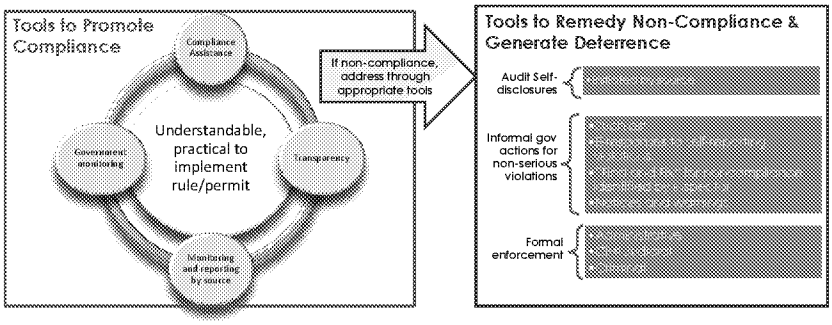
- In order for state inspectors to conduct federal inspections under the Federal Insecticide, Fungicide, and Rodenticide Act they must first attain their Federal Credentials.
  - Inspectors with EPA inspector credentials are the official representatives of EPA to the regulated community
  - It is the responsibility of inspectors to maintain and keep their inspector credentials current
  - For more information on federal credentials please contact the appropriate EPA Contact available on the Inspector Wiki (click Credential & Training Contacts): https://wiki.epa.gov/inspector/index.php/Wiki_Home

OECA Contacts

- In general, call **Office of Civil Enforcement (OCE)**:
  - If the issue deals with an enforcement response, or debate over whether or not to take an enforcement action.
  - Questions about submission of ECRs (enforcement case review requests) and similar case support activities,
  - Questions about other activities relating to taking an enforcement action and settling a case.

OECA Goals

OECA's goal is Compliance and we use a variety of tools to promote compliance and remedy non-compliance.



States and EPA have policies/procedures on the appropriate use of the tools in our compliance assurance tool box, with states taking the majority of actions in authorized programs. We are collaborating to modernize our tools by leveraging advances in pollution monitoring and information technology, sharing best practices, and using social science to develop and evaluate new approaches.

FIFRA Cooperative Agreements

FIFRA authorizes cooperative agreements between EPA and states, territories and tribes to conduct pesticide compliance and enforcement activities.

- Governed, in part, by a Cooperative Agreement Guidance.
  - Joint guidance between OECA and OPP.
  - Provides information and requirements on workplan generation, reporting, etc.
  - Compliance activities include compliance assistance, compliance monitoring and enforcement.

FY 18-21 FIFRA Cooperative Agreement Program Areas for OECA

Required:

- Basic Pesticide Program
- Worker Protection Standard
- Pesticide Applicator Certification
- Pesticides in Water
- Product Integrity
- Border Compliance

Pick-List:

- Fumigation/Fumigants
- Spray Drift
- State and Tribal Coordination and Communication
- Emerging Public Health Pesticide Issues

EPA Regional Support

- OECA can be a helpful resource for State lead agencies, but Regional contacts should be consulted first.
  - EPA Project Officers (PO) are an invaluable resource and have more knowledge on your specific pesticide program.

- EPA Regional Pesticide Contact Information: https://www.epa.gov/pesticide-contacts/pesticide-contacts-our-regional-offices

Key Roles of Project Officers and Technical Contacts

1. **Management/Oversight**
   a. **Cooperative Agreement** – track state and tribal activities throughout the year to make sure commitments are being met
   b. **Fiduciary** – Review budget to make sure proposed expenditures are reasonable
   c. **Primacy** – ensuring adequate laws/regulations and procedures are in place
2. **Conduit/liaison between:**
   a. The state/tribe and the regional/national program;
   b. The state/tribe and the regional grants office
   c. The state/tribe and the public

Resources

- FY 18-22 EPA Strategic Plan

https://www.epa.gov/sites/production/files/2018-02/documents/fy-2018-2022-epa-strategic-plan.pdf

- FY 18-19 OECA National Program Managers Guidance

https://www.epa.gov/sites/production/files/2017-10/documents/fy18-19-oeca-npm-guidance.pdf

- FIFRA Compliance Monitoring Strategy

https://www.epa.gov/sites/production/files/2015-09/documents/fifra-cms.pdf

- FIFRA Inspection Manual

https://www.epa.gov/sites/production/files/2014-01/documents/fiframanual.pdf

- Joint OPP/OECA FY 18-21 Cooperative Agreement Guidance

https://www.epa.gov/compliance/fiscal-year-2018-2021-fifra-cooperative-agreement-guidance

- Compliance Website

https://www.epa.gov/compliance

- FIFRA Enforcement Website

https://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement#chemical

- "Interim OECA Guidance on Enhancing Regional-State Planning and Communication on Compliance Assurance Work in Authorized States"

https://www.epa.gov/compliance/interim-oeca-guidance-enhancing-regional-state-planning-and-communication-compliance

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Contact Information

Office of Pesticide Programs (OPP)

- For the most up-to-date OPP contact information follow this link:
  - https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp

Office of Enforcement and Compliance Assurance (OECA)

- For the most up-to-date OECA contact information follow this link:
  - https://www.epa.gov/aboutepa/about-office-enforcement-and-compliance-assurance-oeca

Regional Pesticide EPA Contacts

- For the most up-to-date Regional contact information follow this link:
  - https://www.epa.gov/pesticide-contacts/pesticide-contacts-our-regional-offices